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- Enter CMPP™ credits earned at the 2019 European Meeting of ISMPP.

- Registration Is Open for the 15th Annual Meeting of ISMPP, themed Communicating Science in an Era of Innovation and Change, April 15-17, National Harbor, MD.
Upcoming 2019 ISMPP Conferences

2019 Asia Pacific Meeting of ISMPP
Mark Your Diaries - 6 September 2019

ISMPP WEST 2019
November 14-15 • San Diego, CA, USA
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Questions

• To ask a question, please type your query into the Q&A box

• To ensure anonymity and that all presenters receive your question, please choose the drop down box option: 
  "Host & Presenters"
  Otherwise, all audience members will be able to see your submitted question

• We will make every effort to respond to all questions

NOTE: Make sure you send your question to: “Host & Presenters”
I recently met a physician from southern Africa engaged in perinatal HIV prevention, whose primary access to information was abstracts posted on the Internet. Based on a single abstract, they had altered their perinatal HIV prevention program from an effective therapy to one with lesser efficacy. Had they read the full-text article they would have undoubtedly realized that the study results were based on short-term follow-up, a small pivotal group and incomplete data, and were unlikely to be applicable to their country’s situation. Their decision to alter treatment based solely on the abstract’s conclusions may have resulted in increased perinatal HIV transmission.

Professor Arthur Ammann
Professor of Pediatrics, University of California San Francisco
Co-founder Global Strategies

Funders Are Embracing Open Access to Maximize Research Impact

http://roarmap.eprints.org; https://libraries.mit.edu/scholarly/research-funders/
Overview & Learning Objectives

At the end of this session, participants should be able to:

• Understand the growing movement towards open access publishing and be aware of the economic considerations and concerns surrounding open access

• Define key elements of open access publishing options and policies (e.g., gold, green and bronze open access models, article versions, embargo periods, Creative Commons licensing options, funders’ open access policies)

• Understand the perspectives on open access of non-commercial and commercial stakeholders in medical research

• Be knowledgeable about the changing open access environment and what the future of open access might look like from the perspectives of key stakeholder groups (publisher, funder, researcher, patient and industry)
Introductions

• **Moderator:** Chris Winchester, DPhil, Chair, ISMPP Board of Trustees (2018–2019); CEO, Oxford PharmaGenesis; Co-founder, Open Pharma

• **Moderator:** LaVerne Mooney, BSc, MPH, DrPH, Director & Team Leader: Publications, CI and Innovation, External Medical Communications, Pfizer; Steering Committee Member, Medical Publishing Insights and Practices (MPIP); Member, Open Pharma
Introductions

- **Joe Adams**, Regional Sales Manager EMEA, Wiley
- **Ashley Farley**, MLIS, Associate Officer of Knowledge & Research Services, Bill & Melinda Gates Foundation
- **J. Britt Holbrook, PhD**, Assistant Professor, Department of Humanities, New Jersey Institute of Technology; Member, European Commission Expert Group on Open Science Indicators
- **Valerie Philippon**, PhD, Senior Director and Global Head, Scientific Publications, Global Medical Affairs, Shire
- **David Sampson**, MBA, Vice President and Publisher, Publishing, American Society of Clinical Oncology (ASCO)
- **Alan Thomas**, Patient Engagement Advocate for Rare Diseases; Founder, Ataxia and Me©
The opinions expressed in this presentation are those of the presenters and do not necessarily reflect the views or policies of current or former employers, nor those of ISMPP.
Fundamentals of Open Access

Chris Winchester
LaVerne Mooney
What is Open Access?

Open access refers to peer-reviewed, full research articles that have been accepted for publication and are available:

- On demand online
- to read without charge to end users

There are varying restrictions on reuse of article content as specified by the copyright licence used, and debates are ongoing as to how open access should best be defined.
Which of the following do you feel best qualifies as ‘open access’?

- Free to read 29%
- Free to read and adapt without restrictions 12%
- Free to read and share without restrictions 23%
- Free to read, reuse and adapt without restrictions 12%
- Free to read non-commercially 36%
What is the most important benefit of open access?

- Accessibility: 47%
- Speed: 31%
- Transparency: 20%
- Avoiding transfer of value: 2%
What are the greatest misunderstandings about open access?

- Confusion surrounding access and copyright licenses
- Less prestigious or even predatory
- Biased towards industry
- Not economically stable
What is the key barrier to wider adoption of open access?

• Costs to the author’s institution or funder
• Current journal model
• Less prestigious reputation
• Restricted journal choice
• Lack of awareness and understanding
• Concerns about predatory journals
Journal Publishing Models

**Subscription**
- Reader pays: subscription or pay-per-article
- Authors transfer copyright to Journal (CTA)

**Hybrid**
- Reader pays OR author pays APC for OA
- Authors transfer copyright to Journal (CTA) OR Author retains copyright if OA option selected

**Open Access**
- Authors pay APC for OA
- Authors retain copyright

APC, article processing charge; CTA, copyright transfer agreement.
# Open Access Options for Individual Articles

<table>
<thead>
<tr>
<th>Availability</th>
<th>Gold</th>
<th>Green</th>
<th>Bronze</th>
</tr>
</thead>
<tbody>
<tr>
<td>Version</td>
<td>Final typeset publication</td>
<td>Submitted version OR final typeset publication</td>
<td>Final typeset publication</td>
</tr>
<tr>
<td>Location</td>
<td>Journal website and/or self-archived</td>
<td>Self-archived (personal/institutional webpages or funder/institutional repositories [e.g. PubMed Central], journal website</td>
<td>Journal website</td>
</tr>
<tr>
<td>Timing</td>
<td>Immediately and forever</td>
<td>After embargo (0, 6, 12 months)</td>
<td>Not disclosed</td>
</tr>
<tr>
<td>Reuse Rights</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Author Fee/Cost</td>
<td>Yes</td>
<td>Not applicable</td>
<td>No Applicable</td>
</tr>
</tbody>
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https://creativecommons.org/licenses/by-nc-nd/4.0/
“Harvest content from legal sources including repositories run by universities, governments, and scholarly societies, as well as open content hosted by publishers themselves.”

- Unpaywall

Make sure to abide by copyright laws associated with documents obtained!
Funders are moving to more open access

- **Green OA**: 12-month embargo
- **Bronze OA**: 6-month embargo
- **Gold OA**: No embargo

**Author archiving (repository)**
- CC BY-NC-ND
- CC BY-NC
- CC BY

**Journal archiving (repository)**
**Journal upload (journal website)**
Funders are moving to more open access

- **Gold OA**: No embargo
- **Bronze OA**: 6-month embargo
- **Green OA**: 12-month embargo

**Author archiving (repository)**

**Journal archiving (repository)**

**Journal upload (journal website)**

License options:
- CC BY-NC-ND
- CC BY-NC
- CC BY
cOAlition S and Plan S

After 1 January 2020 scientific publications on the results from research funded by public grants provided by national and European research councils and funding bodies, must be published in compliant Open Access Journals or on compliant Open Access Platforms.

Criteria for compliant open access journals and platforms include:

- Scholarly content must be openly available immediately upon publication without any embargo
- The journal platform must enable authors to publish under a CC BY 4.0 license
- The “hybrid” model of publishing is not compliant

https://www.coalition-s.org/
Resources

https://openpharma.blog/

https://www.mpip-initiative.org/transparencymatters/openaccess.html
Stakeholder Perspectives
Funders and Open Access

Ashley Farley
Associate Officer of Knowledge & Research Services
Bill & Melinda Gates Foundation (BMGF)
Open Access @ BMGF

• By freely sharing high quality research as soon as it is available, we & our partners can develop more efficient and effective strategies to tackle the problems we are trying to solve.

• Harness advances in technology – ex: Gates Open Research

IF YOU WANT TO GO FAST, GO ALONE.
IF YOU WANT TO GO FAR, GO TOGETHER.

— African proverb
Open Access @ BMGF

- Open Access Policy
  - Immediately available (no embargo)
  - CC-BY license only

- Policy Infrastructure
  - Chronos
  - Data collection
Publishers and Open Access

Joe Adams
Regional Sales Manager EMEA
Wiley
Open Access and Publishers

• Publishers want to publish high quality content and have it read
  – Content from industry tends to be high-quality and as publishers we
    are keen to support good quality content.

• Different types of journal models (subscription, hybrid or open access)
  lend themselves to different copyright and reuse parameters

• It is important that before submission authors and funders understand
  the implications of future use. Pharma companies need to build this
  into their future plans

• Wiley does not add a premium APC for pharma funded article
  submissions

APC = article processing charge
Open Access and Publishers (cont)

My thoughts on open access...

- The only constant will be change in this area (Plan S and Projekt Deal demonstrate this)
- Open access increases article downloads and citations
- Open access allows promotion of these papers to further increase downloads and altmetric scores – which is good for the publisher, reader, author and funder
- Need to carefully assess publishing model changes, as there are many stakeholders involved.
- Open access is just one part of how content is engaged with
Societies and Open Access

David Sampson
Vice President & Publisher
American Society of Clinical Oncology
Societies and Access

- Open access and free access
  - OA option in almost all journals (hybrid)
  - Full gold OA launches
- Developing world access
  - Research4Life HINARI (8900 inst; 120 LMICs)
- Patients and caregivers
  - patientACCESS and patientINFORM
- Public
  - Public libraries, e.g. Access to Research UK

LMIC, low and middle income countries
Societies and Open Access

• Publishing surpluses fund OA and new journals
  – APC-only OA model is currently unsustainable

• Publishing is expensive
  – Technology costs (increasing)
  – Editor stipends; reviewer honoraria; editorial meetings
  – COI disclosures
  – Submission growth increases costs
  – Research communication, e.g. synoptic content
  – Promotion of research, e.g. social media
  – Archiving
Industry and Open Access

Valérie Philippon
Senior Director and Head, Publications
Global Medical Affairs
Shire, now part of Takeda
Industry and Transparency

• Shire and Takeda have a strong culture of transparency and corporate responsibility
• Shire pledged to responsibly share clinical study data in a manner that is consistent with the following principles:
  − Safeguarding the privacy of patients and ensuring that patient perspective remains at the fore
  − Preserving scientific rigor and trust in regulatory systems, and
  − Maintaining incentives for investments in biomedical research
Shire’s Support of Data Sharing Principles

• Data sharing with researchers
• Public access to clinical study information and results
• Sharing results with patients
• Certifying procedures for sharing clinical study information
• Publishing clinical studies
  – Commitment to making every effort to publish clinical study results regardless of the outcome of the clinical trial
  – Shire research manuscripts submitted to journals that are visible to the public via Open Access, preferably with CC-BY license
Two Pharmaceutical Companies have Open Access Policy

Shire Continues to Uphold High Standards of Ethics and Transparency with Adoption of Open Access Policy for Publication of Shire-Supported Research

Cambridge, MA – January 23, 2018 – Shire plc (LSE: SHP, NASDAQ: SHPG), the global leader in rare diseases, has implemented a new publication policy requiring the submission of all Shire-supported research manuscripts to journals that offer public availability via open access, allowing the public to obtain free, unrestricted online access to Shire’s research promptly following publication. Shire’s open access policy, which went into effect on January 2, 2018, was announced today at the 2018 European Meeting of International Society for Medical Publication Professionals (ISMPP) taking place in London, UK, January 23-24.

“Shire’s new open access policy builds on our commitment to transparency and reflects our dedication to helping patients by allowing everyone to freely access and learn from our research findings,” said Christopher Rains, Head, Global Medical Affairs - Medical Shared Services at Shire. “We believe it’s imperative to pioneer a new standard of access to publications that can encourage collaboration and drive medical innovation, with a goal of helping to bring innovative treatments to patients more rapidly. This may be particularly important when it comes to advancing new therapies for treating rare diseases.”

Ipsen commits to making all its published scientific research freely accessible to everyone

We aim to publish the results of our clinical studies in peer-reviewed medical and scientific journals, whatever the outcome. Patients are increasingly engaged with understanding and managing their own healthcare and, as a company, we therefore believe it vital that our research is freely accessible on publication.

However, most journals require a subscription to access their content, meaning that only researchers with affiliations to large academic institutions can freely read the research findings.
Is your organization thinking/in the process of including a Open Access statement in its publication policy?

- Yes
- No
- I don’t know
Academics and Open Access

J. Britt Holbrook
Assistant Professor, Department of Humanities,
New Jersey Institute of Technology
Member, European Commission Expert Group on Open Science Indicators
Academic Freedom and Responsibility

• Freedom
  – Research
  – Teaching

• Responsibility
  – To peers & academic community
  – To society

• Mandates
  – Mandates imposed by others limit one’s freedom
  – Self-imposing a mandate is an exercise of autonomy
  – Funders ≠ universities
Patients and Open Access

Alan Thomas
Patient Engagement Advocate for Rare Diseases
Founder, Ataxia and Me®
My story: Ataxia, associated rare disease and movement disorders

• Ataxia = a Greek word meaning “lack of order”
• Ataxia affects balance, speech and coordination
• Our mission is to bring back some order to the lack of order

Patient focused
“Patients helping patients helping patients”

Alan Thomas – Founder
Ataxia and Me
Open Access and Patients

- Regularly run into paywalls while trying to find high-quality information on my rare disease and to share with other patients
- Patients don’t realize that it is journals locking content behind paywalls
- Pharmaceutical companies can be more open and collaborative by working to make their research open access – might help increase public trust
Audience and Faculty Discussion
Open Access Discussion

• To ask a question, please type your query into the Q&A box
• To ensure anonymity, before sending please choose the drop-down box option, "Hosts and Presenters." Otherwise, ALL audience members will be able to see your submitted question

This Photo by Unknown Author is licensed under CC BY-SA-NC
Key Takeaways for Medical Publication Professionals

LaVerne Mooney
• Most journals allow some form of open access – open access is more than open access journals

• When publishing open access, understand the license and reuse rights obtained, so copyright rules won’t be violated or pay more than needed

• When discussing open access:
  – Be clear about what you mean or want to achieve (free to read or free to read and reuse)
  – Understand license options and cost, and share with your teams
  – Don’t be afraid to ask publishers for what you want

• Budget ahead for open access fees

• Benchmark your costs and types of open access you are choosing

• Maintain the same high level of scrutiny as you would with any journal
Open Access Resources
Open Access Resources

• Berlin Declaration on Open Access
  https://openaccess.mpg.de/Berlin-Declaration

• Bethesda Statement on Open Access Publishing.
  http://legacy.earlham.edu/~peters/fos/bethesda.htm

• Budapest Open Access Initiative: 10 recommendations.
  http://www.budapestopenaccessinitiative.org/boai-10-recommendations

• Cold Springs Harbor Library Open Access site
  https://cshl.libguides.com/c.php?g=474046&p=3243844

• cOAlition S website
  www.scienceseurope.org/coalition-s
Open Access Resources (cont)

• Directory of Open Access Journals
  https://doaj.org/

• Ellison T, Koder T, Schmidt L et al. Open access policies of leading medical journals: a cross-sectional study. Preprint available at: https://www.biorxiv.org/content/early/2018/12/17/250613

• Medical Publishing Insights & Practices (MPIP) open access reference site
  https://www.mpip-initiative.org/transparencymatters/openaccess.html

• Open Access Scholarly Publishers Association: Best practices in licensing and attribution
  https://oaspa.org/best-practices-licensing-attribution-need-to-know/
Open Access Resources (cont)

• Open future: open access presentation by Open Pharma
  https://networkpharma.tv/2018/10/22/open-future-open-access/

• Open Pharma blog
  https://openpharma.blog/

• Plan S press release

Open Access Resources (cont)

- Predatory publishing podcast by Open Pharma
  https://openpharma.blog/2018/10/17/predatory-publishing-on-the-open-pharma-podcast/
- SHERPA/RoMEO (http://www.sherpa.ac.uk/romeo/index.php)

Coming soon... ISMPP open access white paper
# Upcoming ISMPP U

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<thead>
<tr>
<th>DATE</th>
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<tr>
<td>February 27, 2019</td>
<td>Highlights of the 2019 European Meeting of ISMPP</td>
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Thank You for Attending!

• We hope you enjoyed today's presentation.
• **Please check your email for a link** to a survey that should take only a few minutes to complete.
• We depend on your feedback and take your comments into account as we develop future educational offerings. Thank you in advance for your participation!
Faculty Bios
Joe Adams runs the EMEA sales team for direct pharmaceutical sales at Wiley. The main focus of Joe and his team is to enhance the impact of articles and content to develop greater engagement for pharma clients and journals. Joe has a successful background managing teams focusing on larger content solution packages for the pharmaceutical industry. In addition to this Joe manages commercial aspects such as advertising and reprints.
Ashley Farley (Bill & Melinda Gates Foundation)

Ashley Farley has worked over the past decade in both academic and public libraries, focusing on digital inclusion and providing access to scholarly content. She has completed her Masters in Library and Information Sciences through the University of Washington’s Information School. Ashley is an Associate Officer of Knowledge and Research Services. In this capacity, she serves on the core Open Access team, focusing on the foundation’s Open Access Policy’s implementation. This includes the development of Chronos, and leading the implementation of Gates Open Research. Other core activities involve supporting the strategic and operational aspects of the foundation’s library. This work has sparked a passion for open access, believing that freely accessible knowledge has the power to improve and save lives.
J. Britt Holbrook is a philosopher who earned his PhD from Emory University (2004). His postdoctoral research at the University of North Texas (UNT) explored the use of broader societal impacts criteria in the peer review of grant proposals, open access, and the development of quantitative metrics of broader impacts. From 2008 – 2014, Holbrook served as Assistant Director of UNT’s Center for the Study of Interdisciplinarity. After two years (2013 – 2015) as Visiting Assistant Professor in the School of Public Policy at Georgia Tech, Holbrook joined the Department of Humanities at New Jersey Institute of Technology, where he is currently Assistant Professor. In addition to his work on science and technology policy, Holbrook also conducts research on the ethics of science and technology. As a member of the American Association for the Advancement of Science’s (AAAS) Committee on Scientific Freedom and Responsibility (2012 – 2018), Holbrook was one of the co-authors of the AAAS Statement on Scientific Freedom and Responsibility. Throughout 2018, Holbrook served as a member of the European Commission Expert Group on Indicators for Researchers’ Engagement with Open Science and its Impacts.
Valerie Philippon is the Head of Global Publications at Shire, a leading global biotech in rare diseases with medicines in over 100 countries. She leads the publications teams responsible for publications related to all company therapeutic areas (hematology, immunology, oncology, gastrointestinal/internal medicine, neuroscience, ophthalmics, genetic diseases) across various geographies. Valrie has over 20 years of experience in Research, Development, and Medical Communications. She received her Ph.D. in Microbiology from the University Denis Diderot Paris, France and completed a post-doctoral fellowship at Harvard School of Public Health. She has held various Publications and Scientific Communication roles with increasing responsibilities at Idenix, Vertex, AVEO Oncology, and Cubist before joining Shire.
David Sampson is Vice President and Publisher, Publishing for the American Society of Clinical Oncology where he manages a portfolio of journals and meeting publications and heads up licensing. Prior to joining ASCO, he was an Executive Publisher in Elsevier’s health sciences journals division where he had P&L and strategic responsibility for a portfolio of more than 20 journals. He also worked at Lippincott Williams & Wilkins in various leadership roles, including five years as Managing Director of its Asia office in Hong Kong. He was also an Executive Vice President at Conference Archives, now part of CTI Meeting Technology.
Alan Thomas (Rare Disease Patient Advocate)

Alan Thomas is a patient engagement advocate for rare diseases in general and Ataxia in particular. He is known as the 'rare disease warrior' and, as a patient with a 'life-limiting' rare disease, he can convey the patient engagement message from his point of view in all issues regarding the wellbeing of patients. Alan has established a patient-driven and focused group and campaigns at many levels, including patient forums, local and regional health boards, Welsh/UK government organizations, as well as taking part in many global conferences. He received a nomination from the Bevan Foundation in 2015 in the Health and Wellbeing category. He also founded Ataxia and Me©, an on-line resource for all affected by the condition as well as associated rare diseases and movement disorders.
LaVerne Mooney obtained her BSc degree from Galway University, Ireland and was awarded her Master and Doctor of Public Health degrees from Columbia University Mailman School of Public Health, New York. LaVerne assessed the contribution of genetic and environmental factors to breast and lung cancer at Mailman SPH where she was Assistant Clinical Professor of Public Health, Molecular Epidemiology Group. For the last 11 years, LaVerne has been a Director of Publications in Pfizer Medical where she has concentrated on continuous improvement, publication policy best practices and transparency. LaVerne is currently focusing on innovations in publication technology and policies that can improve access and utility to information, such as reduction of publication cycle times and Open Access. She has represented Pfizer as a Steering Committee Member of the Medical Publication Insights and Practice collaboration, has served on the board of the International Society of Medical Publication Professionals, and is a member of the Open Pharma initiative. LaVerne has published about her research and best publication practices in peer-reviewed literature, and is a coauthor of GPP3.
Chris Winchester is Chief Executive Officer of Oxford PharmaGenesis, an independent HealthScience communications consultancy with a strong heritage in publications. Now in its 21st year, Oxford PharmaGenesis employs over 250 communications professionals in Europe, North America and Asia Pacific. Chris is Chair of ISMPP, a founder of Open Pharma, led the development of the AMWA-EMWA-ISMPP Joint Position Statement on the role of the professional medical writer, and has been involved in collaborative research on the value of professional medical writing support. He has a doctorate in Biochemistry, has co-authored articles in the fields of cardiology, gastroenterology and respiratory medicine, and is an Associate Member of Green Templeton College at the University of Oxford.